Patient and Family Involvement

Patient-Reported Safety and Quality of Care in Outpatient Oncology

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Although patients suffer the effects of medical errors and iatrogenic injuries, little is known about their ability to recognize these events. In consumer surveys, as many as 12%–42% of U.S. adults report that they or a loved one experienced a medical injury.[1–4] These data are difficult to interpret because of the open-ended time frame and investigators' inability to corroborate these events. In addition, patients may not share clinicians' definition of iatrogenic injury. A 1997 Harris poll and a recent article by Burroughs et al. documented substantial variation in patients' understanding of terms such as "medical error" and "adverse event."[1,5]

If patients can identify errors and injuries related to medical care, they may have an important and underrecognized role in ensuring safe patient care. Patients and their families seem well positioned for this role: they are present at the point of care and motivated to ensure quality.[6–9] Clearly, some patients lack the ability to participate, particularly during an acute illness. Several national organizations appear optimistic about the possibility that patients can play a meaningful role in patient safety, offering published materials that encourage patients to observe their care, speak up if they observe a problem, and bring along a friend or family member to serve as an advocate.[10–15]

To understand the capacity of patients to identify medical errors, we undertook a multifaceted study comparing different ways to detect adverse events in oncology care. As part of this study, we developed a method that relied on patient and family volunteers ("patient

Article-at-a-Glance

Background: Although patients suffer the effects of medical errors and iatrogenic injuries, little is known about their ability to recognize these events in ambulatory specialty care.

Methods: At a Boston cancer center in 2004, 193 adult oncology patients treated on a chemotherapy infusion unit were interviewed by four patient safety liaisons—volunteers recruited from the organization's Adult Patient and Family Advisory Council.

Results: Among 193 patients, 83 reported 121 incidents. Investigators classified 2 (1%) adverse events, 4 (2%) close calls, 14 (7%) errors without risk of harm, and 101 (52%) service quality incidents. Respondents reported high staff compliance with safe practices such as identity checking (95%). Examining the most serious event described by each of 42 (22%) respondents who reported a recent unsafe experience, investigators classified only one adverse event, 3 close calls, 9 harmless errors, and 27 service quality incidents.

Discussion: Patients' perception of unsafe care was surprising, given the same patients' recognition of consistent application of safe practices, such as the use of two forms of identification before performing tests and administering treatments. Many ambulatory oncology patients also reported poor service quality. The relationship between patient perception of safe care, medical injury, and service quality merits further study.

safety liaisons") to elicit reports from current outpatients in the oncology infusion unit of a Boston cancer center. We hypothesized that current patients might be willing to report errors and injuries to lay volunteers. This report examines the feasibility of using patient safety liaisons to elicit patients' reports of errors and adverse events and characterizes the types of reported incidents.

Methods

Study Site

We conducted a prospective study of adult patients treated on a 46-chair infusion unit at a Boston-based comprehensive cancer center from February through September 2004. The unit accommodated 31,702 unique visits in fiscal year (FY) 2004. Infusion unit staff provided routine and urgent services to adult patients under the care of staff physicians. Patients were treated for a variety of solid tumors, including thoracic, genitourinary, gastrointestinal, head and neck, breast, and gynecologic cancers. Unit staff provided intravenous (IV) administration of chemotherapeutic agents, anti-emetics, hydration, pain medications, blood, and blood components.

Patient Safety Liaison Selection and Training

We developed a patient safety liaison project based on a patient safety rounds program that the risk manager created in 2001 to elicit patient safety hazards from front-line staff. Patient safety liaisons were patients who were recruited by the organization's Adult Patient and Family Advisory Council, screened, and then interviewed by the research team to assess their communication and interviewing skills. Four patient safety liaisons agreed to participate: two participated regularly, and two served as back-up for days when the primary patient safety liaisons were unable to interview patients. Other than receiving parking expenses, they were not paid.

Patient safety liaisons participated in a one-day training program that included didactic presentations about the nature and extent of medical error, a description of the organization's patient safety program, and a facilitated discussion of a training video. They met with the study team to review the interview instrument and to practice using it in role-playing exercises and in supervised patient interviews.

Instrument Development

We developed a two-page interview tool that described the purpose of the interview ("I am a patient… gathering some information from patients with regard to their perceptions of care, specifically about safety"). Patient safety liaisons asked patients standard questions about safe care practices, with a list of structured responses. They asked the following:

1. If staff had used two forms of identification before performing diagnostic tests or providing treatments
2. If the patient knew whom to call in case of an emergency
3. If the patient understood how to take their medications at home and their medication side effects
4. If the patient "experienced anything today or in the recent past that you would perceive as unsafe within your plan of care."

They elicited additional open-ended responses if the respondent identified an unsafe experience, and asked those who identified an unsafe experience if they had brought the incident to anyone's attention. They also asked each patient for "additional comments that you would like to pass on to the safety team to help us in our efforts to continually improve the delivery of safe, quality patient care."

If patients failed to respond or required encouragement or clarification, patient safety liaisons selected from a set of "teaser" questions to help elicit a response. For example, they asked if patients had questions that were unanswered, if test results were communicated in a timely way, and if they believed that the physical environment was safe. The instrument was revised after pilot testing on the basis of patient safety liaisons' advice to clarify the meaning of questions, facilitate its administration, and improve the quality of the data elicited.

Interview Protocol

A patient safety liaison spent 2–4 hours every week on the unit for 29 weeks from February through September 2004. The timing of visits was left to the discretion of the liaison; all visits were completed during weekdays.

Patient safety liaisons conferred each day with the unit nurse manager or charge nurse to identify patients who were too ill or otherwise inappropriate

(for example, emotional upset) to participate on that date. They then approached patients and family or friends ad hoc, offering them the opportunity to be interviewed. They collected no personal information other than the patient's name and length of time receiving care at the cancer center. They guaranteed the confidentiality of patients' comments, except that information about problems ensuring safe care would be communicated to appropriate staff. Because interviews were designed as a quality improvement activity and posed little risk of harm, interviewees or their proxies (a friend or family member) were not required to provide written informed consent. To put patients at ease, they offered in advance to destroy the surveys after the interview if the patient requested. They approached non-English speakers and relied on a family member or friend to interpret. The length of each encounter varied (range, 10 to 30 minutes each).

After each interview day, the patient safety liaisons reviewed their encounters and submitted completed instruments to a member of the study team [D.D. or J.P.]. Potentially unsafe practices or adverse events were reported and acted on immediately. Reports were summarized and entered into a secure database for later coding and analysis.

Responses

Patient safety liaisons approached 202 patients. Six declined to be interviewed because they were completing treatment and ready to leave the facility. Patient safety liaisons honored three patients' requests to discard their completed surveys, yielding a final sample of 193 patients. No patient was interviewed more than once. Response rates to the structured survey questions varied from 71% to 100%. Of the 193 patients, 93 (48%) made 138 open-ended comments about safety or their general care (1–6 reports per patient). Reviewers excluded 17 reports from 10 patients that could not be coded: generic comments that identified no discernible event or episode of care, events that occurred in the distant past, suggestions for improvement, resolved issues, and one report where the reviewers were uncertain about the nature of the event. The remaining 121 reports affecting 83 patients were then coded and analyzed.

Data Coding

Two reviewers [S.N.W., K.S.] independently coded patients' responses to the open-ended questions about unsafe care and patients' suggestions for improvement, using categories adapted from previous studies.[16–19] Reviewers classified adverse events, close calls, medical errors with minimal risk of harm, and service quality incidents, as follows:

- Adverse events were defined as injuries due to medical care rather than the natural course of the illness.
- Close calls were defined as errors with the potential for injury but resulted in no harm.
- Medical errors with minimal risk of harm included tests or treatments that did not plausibly affect the outcome of care.

Reviewers also classified reports such as poor food quality, waits and delays, and poor communication with clinicians as problems with service quality.[20,21] We defined service quality as patients' self-reported experience of poor care in dimensions other than technical attributes related to diagnosis and treatment.

Reviewers classified the severity of the event as little or no evidence of harm, significant (for example, diarrhea, pain), serious (large abscess), or life threatening (anaphylaxis) and its preventability (definitely, probably, probably not, definitely not). They identified the individuals who were most directly involved in or responsible for the event, selecting from a list that included various clinicians, family and friends, "unknown," and a free-text write-in category. The classification categories for service quality incidents included six major categories: waits and delays, poor communication and lack of information, environmental issues and amenities, poor coordination of care, poor interpersonal skills or unprofessional behavior, and lack of respect for patient preferences. Reviewers also noted other service quality problems, such as problems with parking, which did not readily fit in the major categories. In cases for which the available information made it difficult to distinguish between types of events or levels of severity or preventability, reviewers made the assumption that a lower level of event, seriousness, or preventability applied. Differences were resolved by discussion.

Table 1. Patient-Reported Incidents

Type of Event	Number of Incidents		% of Incidents (*N* = 121)	Incidents per 100 Patients (*N* = 193; 95% confidence interval)
Adverse Event	2		1.7	1.0 (0.1–3.7)
Severity				
Serious		0		
Not Serious		2		
Preventability				
Definitely/Probably Preventable		1		
Probably Not Preventable		1		
Serious and Preventable		0		
Close Call	4		3.3	2.1 (0.6–5.3)
Potential Severity				
Serious		2		
Not Serious		2		
Intercepted				
Intercepted		3		
Not Intercepted		1		
Medical Error without Risk of Harm	14		11.6	7.3 (4.0–12.2)
Service Quality Incident	101		83.5	52.3 (42.6–63.6)
Total	121		100.0	62.7 (52.0–74.9)

Data Analyses

We used the kappa statistic to calculate inter-rater reliability of coding prior to reviewer reconciliation; weighted kappa was used for ordinal measures. Agreement was good for preventability (0.66, $p < .001$) and involved party (0.66, $p < .001$). Agreement was excellent for type of incident (0.98, $p < .001$), severity (0.88, $p < .001$), and service quality category (0.89, $p < .001$).

We analyzed incidents elicited by patient safety liaisons and classified by the two reviewers with confidence that the event had probably or definitely occurred as reported. We stratified involved parties by incident type. We tabulated responses to structured survey questions and calculated rates by adjusting the denominator for the number of responses. We analyzed patients' survey responses to questions about staff identification confirmation, whom to call in an emergency, understanding of medications, reports of unsafe care, and staff notification of such incidents, and stratified responses by patient-reported length of time receiving care at the institution. We collected length of care data by category: < 6 months, 6–12 months, 1–≤3 years, 3–<5 years, 5–≤10 years, and ≥10 years. We used bivariable logistic regression models to calculate a test of trend, assigning each time interval a value equal to the midpoint of the interval (for example, < 6 months = .25, 6–12 months = .75). Intervals greater than 10 years were assigned a value of 10. The hospital's Institutional Review Board approved the study protocol in advance.

Results

Adverse Events, Close Calls, and Medical Errors

Among the 193 patients, two (1%) adverse events were reported (Table 1, above). In one case, a magnetic resonance imaging technician placed an IV catheter that subsequently infiltrated. In the other incident, the patient experienced nausea after radiation therapy because he was not treated in advance with an anti-emetic. Neither event was judged serious and only the latter was judged preventable.

Patients also reported four (2%) close calls. In one case, there was no record of a heparin allergy in the patient's medical record. After the nurse hung this medication, the patient notified her of his allergy to it. This

event was coded as potentially serious and intercepted by the patient. In a second potentially serious incident, the patient received an IV infusion containing codeine. Although the patient had no adverse reaction, a previous allergy to codeine was noted in the medical record. In a third incident, the patient and her friend needed to remind her nurse to administer a medication each month. Staff members apparently told the patient that it was too difficult for staff to keep track of this medication and then requested the patient to remind staff. In a fourth incident, the patient noted that patients and visitors sometimes "fiddled" with infusion pumps, including the "silence" button. In these last two incidents, it was difficult to assess the hazard without knowing the medications. However, reviewers judged there was at least the potential for injury.

Table 2. Service Quality Incidents*

Service Quality Categories	No.	%
Waits and delays	34	33.0
Poor communication and information for patients	22	21.4
Poor coordination of care among staff	13	12.6
Environmental issues and amenities	12	11.7
Poor interpersonal skills and unprofessional behavior	5	4.9
Lack of respect for patient needs and preferences	5	4.9
Other service quality problems		
Problems with parking	6	5.8
Concerns about security	5	4.9
Inadequate staffing	1	1.0
Total*	103	100.0

* Total exceeds 101 incidents because two patients identified two types of service quality lapses in a single report.

Fourteen of the remaining events were errors in care with little risk of harm, a rate of 7%. In one case, it took a nurse six attempts to place a peripheral IV. In another case, the patient had an unnecessary computerized tomography (CT) scan that was prompted by a laboratory error. The same patient needed to provide a second stool sample to the laboratory because the first sample was not processed. Another patient was prepared for an office-based treatment, but the procedure was rescheduled because the nurse practitioner who was to perform the treatment was unavailable. Another patient experienced a treatment delay because the physician orders had not been completed. Another patient identified a problem with an IV infusion. The nurse later noted the slow drip rate and adjusted the equipment so that it functioned properly.

Service Quality Incidents

The remaining 101 incidents involved lapses in service quality, a rate of 52% (Table 2, above). Waits and delays accounted for one-third of service incidents. "Everything takes five times longer than it should," according to one patient. Another reported that it takes five hours for every 20-minute treatment. Patients reported waiting for physicians, laboratory tests, infusion chairs, admission to the hospital, and appointment scheduling. Most reports identified no cause for the delay.

Patients desired better information about their care in 21% of the service incidents. For example, one patient did not know how to access urgent care on a holiday or weekend. Another patient missed a CT scan because of miscommunication regarding the appointment. Another did not know how to get from the doctor's office to the infusion area. Patients identified problems with environmental issues and amenities in 12% of these reports. For example, they noted that elevators are "slow and cramped" and that coffee and snacks "run out" in the afternoon.

Patients also reported poor coordination of care in 13% of service incidents. One patient received different answers to the same question from various clinicians. Another patient, who had worked with six different nurses, wished that the same infusion room nurse could care for her at every appointment. "If they don't know you, they just hang the chemo bag and leave." The remaining reports addressed rude or unprofessional behavior (for example, an argumentative CT technician, facilitators need better "people skills"), and "other" issues, such as difficulty with parking and concerns about security.

Involved Parties

Table 3 (page 88) shows the involved parties by type of incident. The nurse, clinic assistant or facilitator, and

Table 3. Involved Parties

Party	Adverse Event	Close Call	Harmless Medical Error	Service Quality Incident	Total
Attending oncologist	1	0	1	17	19
Nurse	0	2	5	8	15
Clinic assistant or facilitator	0	0	1	8	9
Pharmacist	0	0	0	2	2
Family member or friend	0	1	0	0	1
Phlebotomist	0	0	1	0	1
Other	1	1	2	21	25
Unknown	0	0	4	47	51
Not applicable	0	0	0	2	2
Total*	2	4	14	105	125

* Totals exceed 121 because multiple parties were involved in several events.

attending oncologist were involved in one-third of the service quality incidents. In about 40% of the cases, investigators were unable to identify the involved party.

Safe Practices and Unsafe Care

Patients' responses to the structured safety survey questions demonstrated consistent use of safe practices (Table 4, page 89). However, *22% of the patients responded affirmatively when asked if they experienced a recent unsafe episode in their plan of care.* In five cases, patients had not and were not planning to notify anyone about the incident. One patient did not know whom to tell. Another wanted to remain anonymous. A third patient did not think it would help, and therefore did not want to bother a doctor or nurse. Two other patients offered no explanation.

We then examined the most serious incident reported by each of the 42 patients who identified an "unsafe episode." These 42 reports (Table 5, pages 90–92) included one of two reviewer-classified adverse events (infiltrated peripheral IV catheter), 3 of 4 close calls, and 9 of 14 medical errors with little risk of harm.

In contrast, reviewers classified 27 reports of the 42 patients with "unsafe episodes" as service quality incidents. Reviewers excluded two additional "unsafe" incidents because there was insufficient information to classify the event. In one case, the patient's wife thought the patient would benefit from participating in a support group. In the other, the patient described an issue (not further explained) with an indwelling central venous catheter, which prompted him to switch nurses and infusion dates. Overall, investigators confirmed no adverse event, close call, or harmless error among 29 (69%) of the 42 patients who reported "unsafe episodes." In bivariable analyses, patients who received care at the center for more than three years were more likely to report a recent experience of unsafe care than patients with a shorter duration of care (test of trend, p =.006; Table 6, page 93).

Discussion

Although one in five ambulatory oncology infusion patients reported a recent unsafe experience, investigators judged that only 31% of these patients identified an adverse event, close call, or error with minimal risk of harm. The study team classified most reports of unsafe care as service quality problems, including waits and delays, faulty communication with clinicians, poor coordination among providers, and dissatisfaction with the physical environment and clinic amenities.

Patients' perception of unsafe care was surprising, given the same patients' recognition of consistent application of safe practices, such as the use of two forms of identification before performing tests and administering treatments. Most patients expressed confidence in their knowledge of their medications and about what to do in an emergency. Patients' critical assessment was also inconsistent with the low rate of errors and injuries. More than one in five patients reported an unsafe care

Table 4. Survey Results

Question	No./No. responding	% (95% confidence interval)
Does staff confirm two methods of identification whenever you are having blood drawn, a diagnostic test, or a medication administered?	183/193	94.8 (90.7–97.5)
Do you know who and how to call in an emergency situation?	124/143	86.7 (80.0–91.8)
Do you know how to take your medications at home and their side effects?	133/137	97.1 (92.7–99.2)
Did you experience anything today or in the recent past that you would characterize as an unsafe episode in your plan of care?	42/193	21.8 (16.2–28.3)
Would you have brought this incident to anyone's attention?*	36/41	87.8 (73.8–95.9)

* One patient who reported unsafe care did not answer this question.

experience, but clinician reviewers classified only 1% of these patient reports as care-related injuries and 2% as close calls. Why do patients perceive their experience is unsafe when the risk of harm appears to be small?

There are several possible explanations. First, reporting bias may be present. Experienced patients were more likely to report episodes of unsafe care, perhaps because they had more opportunities to be harmed. A "recent" event for an experienced patient may reflect months or years of care, whereas a "recent" event for a newly diagnosed patient may be limited to days to weeks. In addition, experienced patients may recognize lapses in care more readily than do new patients. Finally, experienced patients, with established relationships with their caregivers, may worry less that providing critical feedback will jeopardize this relationship or affect their treatment.

Second, patients' interpretations of "unsafe" care may differ from the interpretations of health professionals and the research team. The vocabulary of patient safety is confusing to patients,[1] and we offered no explicit definition. An "unsafe" experience "within your plan of care" conjured up problems with parking, concerns about security, as well as waits and delays. Indeed, patients may include emotional injuries as a form of harm.[22]

Third, patients may equate service quality deficiencies with unsafe care. Patients may perceive that these inconveniences signal problems with the overall process of care. If the pharmacy experiences chronic delays, how do we trust that the chemotherapy is prepared reliably? If the nurse and doctor do not communicate well, wouldn't this increase the risk of a serious mishap? Studies of hospitalized patients show that patients are able to distinguish technical quality from various dimensions of service quality.[5–9] However, little is known about the relationship between patients' perceptions of care and the quality of delivered care using standard benchmarks.[23–25] Service quality lapses may, at minimum, undermine patients' trust in their care environment.

The rate of patient-identified adverse events in this study (1%) is similar to the 3% rate for adverse drug events that was recently found in a study using intensive data collection methods and conducted at the same institution.[26] In studies of patients hospitalized in acute care hospitals in the United States, Australia, Canada, and Great Britain, 4%–16% of patients experienced adverse events.[27–31] In consumer surveys, up to 42% of respondents identified an error or injury affecting their care or the care of a loved one.[1–4] These results are difficult to compare, given the possibility of response bias and the lack of a defined reference period. In a prospective survey of adverse events among hospitalized patients, investigators found that 8% of patients identified an adverse event during their admission.[19] In a retrospective chart review and patient interview study of four Boston-based primary care practices, adverse drug events (a subset of all adverse events) affected 25% of patients.[32] Although the rate of adverse events in this study is lower than the rates in these other studies, comparisons are difficult, given differences in methods and patient populations.

Our study has several limitations. Because it was conducted at a single cancer center, its generalizability

Table 5. Patient-Reported "Unsafe" Experiences*

Report	Told Someone	Incident Type	Reviewer Certainty	Involved Party	Classification
At another hospital, patient had an issue with an MRI. The technician missed the vein for the MRI, which led to an infiltration in the tissue. The patient was given three ice packs and sent home. Patient was uncomfortable and had to stop on the way home to get more ice packs.	Yes	Adverse event	Yes	Other	Other
Patient takes a medication once a month. She or her friend who accompanies her has to remind R.N. to give medication. Patient was told that it was too difficult to track this medication in her record. Patient and her friend are R.N.s.	Yes	Close call	Yes	Nurse	Missed or late dose
Patient has an allergy to heparin and it wasn't noted in the medical record. The R.N. hung heparin and the patient asked if it was heparin and when the R.N. said yes, the patient said they were allergic. It was not the patient's primary R.N. that day.	Yes	Close call	Yes	Nurse	Known allergy
When patient was at another hospital he or she was given medication that included codeine, and codeine is listed as an allergy for this patient. Patient noticed that the IV bag said contents contain codeine.	Yes	Close call	Yes	Other	Known allergy
Patient not comfortable with the security requirement at the entrance to the cancer center. Did not like the idea of having to show cancer center ID card. Much better now than it was.	Yes	Medical error	Yes	Nurse	Other
Computer order issue, eventually was resolved that day. Medication delay because orders were not in.	Yes	Medical error	Yes	Attending	Failure to order drug
Coordination problem with outside hospital that provides shot on regular basis.	Yes	Medical error	Yes	Unknown	Failure to order drug
When patient was receiving an IV drip, the IV was not fastened tightly and it went slowly. R.N. then noticed it when they came over to take it away. The infusion should have been done, but R.N. then noticed that it needed to be tightened, and tightened it.	No	Medical error	Yes	Nurse	Missed or late dose
Patient states that R.N. does not always wear gloves when taking blood. Patient experienced contamination at another hospital so very aware of this.	Yes	Medical error	Yes	Nurse	Other
One time, patient did not have an ID bracelet.	Yes	Medical error	Yes	Clinic ass't or facilitator	Other
Patient had an issue with a lab sample. Patient provided a stool sample twice, but the test required was not completed. Patient advised R.N.	Yes	Medical error	Yes	Other	Lost specimen
Patient had two drugs with one port and they were administered simultaneously. The second R.N. told the patient that they should have only one port at a time per medication. It was corrected the next time.	Yes	Medical error	Yes	Nurse	Other medication-related

Table 5. Patient-Reported "Unsafe" Experiences* *(continued)*

Report	Told Someone	Incident Type	Reviewer Certainty	Involved Party	Classification
When patient gets IV starts, sometimes the R.N. keeps trying and won't ask someone else to try.	Yes	Medical error	No	Not coded	Not coded
Patient is uneasy about the small stool used to step up on in the exam room. Has mentioned this to the M.D. Patient states that they think their M.D. "thinks my elevator doesn't go to the top floor."	Yes	Service quality	Yes	Other	Lack of respect for patient preferences
Wait time is a problem. Don't overbook. Tell patient the time is taken.	Yes	Service quality	Yes	Clinic ass't or facilitator	Waits and delays
Waiting is a concern.	No	Service quality	Yes	Unknown	Waits and delays
Waiting for the M.D. is a concern. Causes the patient's blood pressure to rise.	Yes	Service quality	Yes	Attending	Waits and delays
No safety concerns. Concerned about making appointments. Takes 45 minutes to schedule appointments. Feels everything takes 5 times longer than it should. Big difference between the cancer center and a nearby hospital. Much better at the nearby hospital, and follow-up also.	Yes	Service quality	Yes	Other	Waits and delays
Patient is from Northern Maine and had an issue with getting an appointment. Patient did complain and the issue was addressed.	Yes	Service quality	Yes	Clinic ass't or facilitator	Waits and delays
Waiting	Yes	Service quality	Yes	Pharmacist	Waits and delays
In the patient bathrooms there are no toilet seat covers. Patients are weak and cannot stand and do not want to sit on dirty toilet seats.	Yes	Service quality	Yes	Other	Environmental issues
Elevator doors stay open for too short a time and close too abruptly and are very heavy.	No	Service quality	Yes	Unknown	Environmental issues
Elevators are slow and small and patients have to wait a long time for them. Patient thinks she is getting great care and staff is very friendly and answers questions.	Yes	Service quality	Yes	Unknown	Environmental issues
Elevators close too quickly. Bathroom doors are very heavy. Patient noted that both of these could cause problems for a patient who is weak, with IV poles, walkers, etc. Patient is a physical therapist.	Yes	Service quality	Yes	Other	Environmental issues
Toilet seat was loose recently. R.N. and Nurse Manager notified.	Yes	Service quality	Yes	Other	Environmental issues
Not all toilets have seat tissues.	Yes	Service quality	Yes	Other	Environmental issues
Not getting a real person to answer the phone. Calling M.D. and getting machine.	Yes	Service quality	Yes	Attending	Environmental issues

Table 5. Patient-Reported "Unsafe" Experiences* *(continued)*

Report	Told Someone	Incident Type	Reviewer Certainty	Involved Party	Classification
Patient not informed that clinical trial was full until arrived here from Florida for an appointment. Called before to ensure the trial was open. Someone did drop out from the trial and patient was able to enroll.	Yes	Service quality	Yes	Other	Poor communication
After 1st Taxol® (paclitaxel) treatment, patient did not know what to expect. Pain meds were not explained or available.	Yes	Service quality	Yes	Attending	Poor communication
Patient was in an infusion chair. Mechanism results in jolt when placed in reclined position and patient cannot move chair to upright/exit position without assistance.	Yes	Service quality	Yes	Nurse	Poor communication
Patient states that they are not educated on how to get the results of a test or exam. Often have to go and seek out the results on their own or they are not called in a timely fashion. This raises concerns for the patient.	No	Service quality	Yes	Attending	Poor communication
Patient feels that there could be better communication between M.D.s at outside hospital and cancer center. Says this as a result of being in an emergency at the outside hospital.	Yes	Service quality	Yes	Unknown	Poor coordination
Hard to get the same R.N. It is nice to have the same person [on subsequent visits]. Makes patient feel more secure.	Yes	Service quality	Yes	Unknown	Poor coordination
Patient thinks parking spaces are too small. Has experienced two accidents in Smith garage. 5th floor-bottom ramp right side, hit the post on two occasions.	Yes	Service quality	Yes	Other	Parking
Parking spots too small in garage. Patient hit a pole.	Yes	Service quality	Yes	Other	Parking
Parking garage is a challenge.	Yes	Service quality	Yes	Other	Parking
Parking is very tight physically. The nearby garage should be saved for patients only so that there is no need to cross the street.	Yes	Service quality	Yes	Other	Parking
Patient concerned about walking down the stairway from the parking garage in the early morning before an appt- is it checked by security that early?	Yes	Service quality	Yes	Other	Security
Overcrowding in infusion area.	No	Service quality	Yes	Unknown	Security
Too crowded.	Yes	Service quality	Yes	Unknown	Security
Patient changed R.N. Had an issue with an indwelling central venous catheter. Patient told M.D. and ended up switching days and R.N.s. The patient asked for a specific R.N. and was assigned to that one. The patient felt this was handled well.	Yes	Exclude	Not coded	Not coded	Not coded
Patient requested a support group for her husband. He always feels like he is not doing enough.	No response	Exclude	Not coded	Not coded	Not coded

*MRI, magnetic resonance imaging; IV, intravenous.

Table 6. Patient Survey, by Length of Time Receiving Care at the Hospital

		< 6 mos	6 mos to < 1 yr	1 yr to < 3 yrs	3 yrs to < 5 yrs	5 yrs to < 10 yrs	≥ 10 yrs	Not available	Total	*p* value test of trend
Question										
Does staff confirm two methods of identification?	*n*	61	21	41	17	18	12	13	183	.926
	%	89.7	100.0	100.0	94.4	94.7	92.3	100.0	94.8	
	N	68	21	41	18	19	13	13	193	
Do you know who and how to call in an emergency situation?	*n*	42	13	26	12	13	7	11	124	.858
	%	89.4	100.0	83.9	85.7	92.9	63.6	84.6	86.7	
	N	47	13	31	14	14	11	13	143	
Do you know how to take your medications at home and their side effects?	*n*	44	10	30	13	13	10	13	133	.785
	%	97.8	100.0	100.0	92.9	92.9	90.9	100.0	97.1	
	N	45	10	30	14	14	11	13	137	
Did you experience an unsafe episode in your plan of care?	*n*	12	4	6	7	8	5	0	42	.006
	%	17.6	19.0	14.6	36.8	42.1	38.5	0	21.8	
	N	68	21	41	19	19	13	12	193	
Would you have brought this incident to anyone's attention?	*n*	11	4	5	4	8	3	1	36	.731
	%	91.7	100.0	83.3	66.7	100.0	75.0	100.0	87.8	
	N	12	4	6	6	8	4	1	41	

to other locations and other patient populations is unknown. A few highly motivated and experienced patient volunteers served as patient safety liaisons. These volunteers were accustomed to the role of patient advocate, rather than researcher, and actively elicited subjects' responses and observations. Although we encouraged patient safety liaisons to approach any patient on the unit (other than those excluded by the nurse manager), we do not know if bias affected their selection of interviewees or the way they framed survey questions. For example, some of the "teaser" questions used to illustrate patient safety problems might have preferentially elicited service quality issues. We also cannot assess the accuracy of data reporting because interviews were not monitored. Clinician coders classified reports that were collected by patient safety liaisons and then paraphrased by investigators. Taped reports would have provided more accurate information, but this approach was actively discussed with the patient safety liaisons and rejected.

Despite these limitations, the study adds to our growing knowledge about the roles that patients may play in patient safety.[19,33] It provides proof of principle that patient volunteers can elicit information from other patients about the quality and safety of their care. It also suggests that patients may regard service quality lapses as an indication of problems with their care. The lapses, in turn, may signal to patients that care may be unsafe. This association between patient perception of safe care, medical injury, and service quality merits further study. J

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References

1. National Patient Safety Foundation: *Public opinion of patient safety issues: Research findings. Report prepared by Louis Harris and Associates for the National Patient Safety Foundation at the AMA.* Sep. 1997. http://www.npsf.org/download/1997survey.pdf. (last accessed Dec. 4, 2006).
2. How safe is your hospital? Consumer reports readers rate the care they or a relative received. *Consumer Reports* 68:12–18, Jan. 2003.
3. Blendon R.J., et al.: Views of practicing physicians and the public on medical errors. *N Engl J Med* 347:1933–1940, Dec. 12, 2002.
4. Altman D.E., Clancy C., Blendon R.J.: Improving patient safety: Five years after the IOM report. *N Engl J Med* 351:2041–2043, Nov. 11, 2004.
5. Burroughs T.E., et al.: Patients' concerns about medical errors during hospitalization. *Jt Comm J Qual Patient Saf* 33:5–14, Jan. 2007.
6. Davies R.D., Ware J.E.: Involving consumers in quality of care assessment. *Health Aff (Millwood)* 7:33–48, Spring 1998.
7. Cleary P.D., et al.: Patients evaluate their hospital care: a national survey. *Health Aff (Millwood)* 10:254–267, Winter 1991.
8. Cleary P.D., Edgman-Levitan S.: Health care quality: Incorporating consumer perspectives. *JAMA* 278:1608–1612, Nov. 19, 1997.
9. Cleary P.D.: A hospitalization from hell: A patient's perspective on quality. *Ann Intern Med* 138:33–39, Jan. 7, 2003.
10. Institute for Family-Centered Care: *Your Role in Safe Medication Use.* Boston: Massachusetts Coalition for the Prevention of Medical Errors, 1999. http://www.macoalition.org/documents/Best_Practice_Medication_Errors.pdf (last accessed Dec. 4, 2006).
11. American Hospital Association: *Successful Practices for Improving Medication Safety, 1999.* http://www.hospitalconnect.com/aha/key_issues/medication_safety/ahainitiative/medicalsafety20015.html (last accessed Dec. 4, 2006).
12. National Patient Safety Foundation: *You Can Help Improve Patient Safety (Consumer Fact Sheet).* http://www.npsf.org/download/ConsumerFactSheet.doc. (last accessed Dec. 6, 2006).
13. National Patient Safety Foundation: *National Agenda for Action: Patients and Families in Patient Safety, 2003.* http://www.npsf.org/download/AgendaFamilies.pdf (last accessed Dec. 4, 2006).
14. Agency for Healthcare Research and Quality: *Patient Fact Sheet: 20 Tips to Help Prevent Medical Errors.* AHRQ Publication No. 00-PO38, Feb. 2000. http://www.ahrq.gov/consumer/20tips.htm (last accessed Dec. 5, 2006).
15. Joint Commission on Accreditation of Healthcare Organizations. *Speak Up: Facts About Speak Up Initiatives.* http://www.jointcommission.org/GeneralPublic/Speak+Up/about_speakup.htm (last accessed Dec. 5, 2006).
16. Bates D.W., et al.: Incidence of adverse drug events and potential adverse drug events: Implications for prevention. *JAMA* 274:29–34, Jul. 5, 1995.
17. Weingart S.N., Ship A.N., Aronson M.D.: Confidential clinician-reported surveillance of adverse events among medical inpatients. *J Gen Intern Med* 15:470–477, Jul. 2000.
18. Weingart S.N., et al.: A physician-based voluntary reporting system for adverse events and medical errors. *J Gen Intern Med* 16:809–814, Dec. 2001.
19. Weingart S.N., et al.: What can hospitalized patients tell us about adverse events? Learning from patient-reported incidents. *J Gen Intern Med* 20: 830–836, Sept 2005.
20. Kenagy J.W., Berwick D.M., Shore M.F.: Service quality in health care. *JAMA* 281:661–665, Feb. 17, 1999.
21. Mayer T., Cates R.J.: Service excellence in health care. *JAMA* 282:1281–1283, Oct. 6, 1999.
22. Kuzel A.J., et al.: Patient reports of preventable problems and harms in primary health care. *Ann Family Med* 2: 333–340, Jul.–Aug., 2004.
23. Kane R.L., Maciejewski M., Finch M.: The relationship of patient satisfaction with care and clinical outcomes. *Med Care* 35:714–730, Jul. 1997.
24. Schneider E.C., et al.: National quality monitoring of Medicare health plans: The relationship between enrollees' reports and the quality of clinical care. *Med Care* 39:1313–1325, Dec. 2001.
25. Landon B.E., et al.: Comparison of performance of traditional Medicare vs Medicare managed care. *JAMA* 291:1744–1752, Apr. 14, 2004.
26. Gandhi T.K., et al.: Medication safety in the ambulatory chemotherapy setting. *Cancer* 104:2477–2483, Dec. 1, 2005.
27. Brennan T.A., et al.: Incidence of adverse events and negligence in hospitalized patients. *New Engl J Med* 324:370–376, Feb. 7, 1991.
28. Thomas E.J., et al.: Incidence and types of adverse events and negligent care in Utah and Colorado. *Med Care* 38:261–271, Mar. 2000.
29. Vincent C., Neale G., Woloshynowych M.: Adverse events in British hospitals: Preliminary retrospective record review. *BMJ* 322:517–519, Mar. 3, 2001.
30. Wilson R.M., et al.: The quality in Australian health care study. *Med J Aust* 163:458–471, Nov. 6, 1995.
31. Baker G.R., Norton P.G., Flintoft V.: The Canadian Adverse Events Study: The incidence of adverse events among hospital patients in Canada. *CMAJ* 170:1678–1686, May 25, 2004.
32. Gandhi T.K., et al.: Adverse drug events in ambulatory care. *New Engl J Med* 348:1556–1564, Apr. 17, 2003.
33. Weingart S.N., et al.: Lessons from a patient partnership intervention to prevent adverse drug events. *Int J Qual Health Care* 16: 499–507, Dec. 2004.